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Anne-Gaelle Brachet

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JUNEAU PARTNERS

333 N Fairfax St.

Suite 305

ALEXANDRIA, VA 22301

EXAMINER

WILDER, CYNTHIA B

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/553,603	Applicant(s) BRACHET ET AL.	
	Examiner CYNTHIA B. WILDER	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 September 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-69 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40-69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 September 2010 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendment filed 9/27/2010 is acknowledged and has been entered. Claims 1-39 have been cancelled. Claims 40-69 have been added. Claims 40-49 are pending. All of the arguments have been thoroughly reviewed and considered but are deemed moot in view of the new grounds of rejections necessitated by Applicant's amendment of the claims. Any rejection not reiterated in this action has been withdrawn as being obviated by the amendment of the claims.

This action is made FINAL.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Previous Rejection

3. The objection to the drawings is withdrawn in view of Applicant's submission of new drawings. The objections to specification are withdrawn in view of Applicant's submission of a substitute specification with necessary corrections. the claim rejection under 35 USC 101 directed to claim 21 is withdrawn in view of Applicant's cancellation of the claims. The claim rejection under 35 USC 112 second paragraph directed to claims 1-20 and 37-39 are withdrawn in view of Applicant's cancellation of the claims. The prior art rejection under 35 USC 102(b) directed to claims 1-4, 6-23 and 37-39 as being anticipated by Sapolsky et al is withdrawn in view of Applicant's cancellation of the claims. The prior art rejection under 35 USC 102(b) directed to claims 1-4, 6-23 and 37-39 as being anticipated by Jones is withdrawn in view of Applicant's cancellation of the claims. The prior art rejection under 35 USC 102(b)

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directed to claims 1-4, 6-23 and 37-39 as being anticipated by Yu et al is withdrawn in view of Applicant's cancellation of the claims. The prior art rejection under 35 USC 102(b) directed to claims 1-4, 6-23 and 37-39 as being anticipated by Van Eijk et al is withdrawn in view of Applicant's cancellation of the claims. The prior art rejection under 35 USC 102(b) directed to claims 1-4, 6-23 and 37-39 as being anticipated by Kato et al is withdrawn in view of Applicant's cancellation of the claims. The prior art rejections under 35 USC 103(a) directed to claim 5 as being anticipated by any one of Sapolsky et al, Jones, Yu or Van Eijk et al in view of Keith et al is withdrawn in view of Applicant's cancellation of the claims.

New Ground(s) of Rejections

THE NEW GROUND(S) OF REJECTIONS WERE NECESSITATED BY APPLICANT'S AMENDMENT OF THE CLAIMS:

Claim Objections

4. Claim 1 is objected to because of the following informalities:

(a) Claim 1 is objected because there appears to be a typo at step a) in the claim 1 at "reparing". It cannot clearly be determine if Applicant intends "repairing" or "preparing". Appropriate correction is required.

(b) Claim 1 lacks proper spacing at "AA'and" in line 4 of step b) of the claim 1. Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 40-56 and 60-69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a) Claims 40-56 and 60-69 are vague and indefinite in the step b) of claim 40 because it is unclear as to what junction is considered to be the complementary end of the adapter and 5' end of the DNA fragment F1. It is unclear if the step (b) is intended to suggest that both ends of the DNA fragments F1 have blunt or cohesive ends and ligations occurs as both ends of the DNA fragments F1 with the adaptor or that only the 5' end of the DNA fragments F1 have blunt ends that are complementary to the adapters. Additionally, the step (b) is confusing and indefinite because it is unclear as to the structure of the junction sequence as recited in the claim 40. The limitation at the step b) of claim 40 appears to suggest that the junction sequence contains sequences of both the recognition site of an E1 and E2 enzyme, but only cleave at the site containing an E2 recognition enzyme site (step c)). Likewise, limitation in the step (b) appear to contradict the limitation in step (c)) because the step b) recites that the entire sequence of the recognition site of a restriction enzyme E2 is not present, but step c) recites that cleavage occurs at the recognition site of the restriction enzyme E2 using an E2 restriction enzyme. A clear interpretation cannot be ascertained because one

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cannot envision the structure of the composition as recited therein. Clarification is required.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 40-69 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14, 25 of copending application 12/458610.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F. 2d 887, 225 USPQ 645 (fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from other because both the claims 40-69 of the instant invention and the claims 1-14 and 25 of copending application 12/458610 are drawn to a method of preparing DNA fragments and are related because of a genus species relationship. The claims 40-69 of the instant invention falls entirely within the scope of the claims 1-14 and 25 of copending application 12/458610. As the court stated in *In re Goodman*, 29 USPQ2d 2010 (CAFC 1993), "a second application-- "containing a broader claim, more generic in its character than the specific claim in the prior patent"--typically cannot support an independent valid patent. *Miller*, 151, U.S. at 198; See *Stanley*, 214 F.2d at 153. Thus, the generic invention, as noted above is "anticipated" by the species of the

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patented invention. Cf., *Titanium metal corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985) (holding that an earlier species disclosure in the prior art defeats any generic claims). This court's predecessor has held that, without a terminal disclaimer, the species claims preclude issuance of the generical application. "*In re Van Ornum*, 686 F.2d 937, 944, 214 USPQ 761, 767 (CCPA 1982); *Schneller*, 397 F.2d at 354".

This is a provisional obviousness type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

9. The following are new grounds of rejections necessitated by Applicant's amendments. Although the claims were previously rejected as being anticipated by the same reference(s), Applicant's amendments have necessitated the inclusion of new grounds of rejections in the present rejection. It is noted that, to the extent that they apply to the present rejection; Applicant's arguments are addressed following the rejection.

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 40-43, 45-69 are rejected under 35 U.S.C. 102(b) as being anticipated by Sapolsky et al (20030008292, January 2003). With regards to claims 40-43, 45-69, these claims are drawn to a method comprising: preparing double stranded DNA

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fragments using at least one restriction enzyme to generate DNA fragments less than 1000 bp with blunt or cohesive ends; ligating the ends of said fragments to an adaptor comprising a recognition site for the restriction enzyme, the cleavage site of which is located downstream of said recognition site; cleaving the fragments at the 5'-end using a restriction enzyme and purifying said fragments. The claims optionally include additional adapters, amplification of the fragments linked to said adapters with suitable primers. The claims encompass appropriate labels and immobilization to a solid support.

Sapolsky et al teach such a method as pages 2-9 and in the Figures 2 and 3. Therefore, Sapolsky et al meet the limitations of the claims as broadly written.

12. Claims 40-43, 45-69 are rejected under 35 U.S.C. 102(b) as being anticipated by Yu et al (WO 0234939, May 2002). With regards to claims 40-43, 45-69, these claims are drawn to a method comprising: preparing double stranded DNA fragments using at least one restriction enzyme to generate DNA fragments with blunt or cohesive ends; ligating the ends of said fragments to an adaptor comprising a recognition site for the restriction enzyme, the cleavage site of which is located downstream of said recognition site; cleaving the fragments at the 5'-end using a restriction enzyme and purifying said fragments. The claims optionally include additional adapters, amplification of the fragments linked to said adapters with suitable primers. The claims encompass appropriate labels and immobilization to a solid support.

Yu et al teaches such a method as pages 5-6 and 11-15. Therefore, Yu et al meet the limitations of the claims as broadly written.

13. Claims 40-43, 45-69 are rejected under 35 U.S.C. 102(b) as being anticipated by Van Eijk et al (WO 0149882, July 2001). With regards to claims 40-43, 45-69, these claims are drawn to a method comprising: preparing double stranded DNA fragments using at least one restriction enzyme to generate DNA fragments with blunt or cohesive ends; ligating the ends of said fragments to an adaptor comprising a recognition site for the restriction enzyme, the cleavage site of which is located downstream of said recognition site; cleaving the fragments at the 5'end using a restriction enzyme and purifying said fragments. The claims optionally include additional adapters, amplification of the fragments linked to said adapters with suitable primers. The claims encompass appropriate labels and immobilization to a solid support.

Van Eijk et al et al teaches such a method as pages 1-10, 24-25 and 27-28. See also Figures 1-3. Therefore, Van Eijk et al meet the limitations of the claims as broadly written.

14. Claims 40-43, 45-69 are rejected under 35 U.S.C. 102(b) as being anticipated by Kato (EP 0735144, October 1996, citation made of record on IDS). With regards to claims 40-43, 45-69, these claims are drawn to a method comprising: preparing double stranded DNA fragments using at least one restriction enzyme to generate DNA fragments with blunt or cohesive ends; ligating the ends of said fragments to an adaptor

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comprising a recognition site for the restriction enzyme, the cleavage site of which is located downstream of said recognition site; cleaving the fragments at the 5'end using a restriction enzyme and purifying said fragments. The claims optionally include additional adapters, amplification of the fragments linked to said adapters with suitable primers. The claims encompass appropriate labels and immobilization to a solid support.

Kato teaches such a method as pages 5-6 and 11-13. See also Figures 1-3. Therefore, Kato meets the limitations of the claims as broadly written.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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17. Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over any one of Sapolsky et al, Yu, Kato et al or Van Eijk et al as previously described above in view of Keith et al (US 5093245). With regards to claim 5, this claim is drawn to a method as described and rejected above, further wherein the steps (a) and (b) are carried out simultaneously.

None of the references previous discussed above teach wherein the steps of restriction digestion and ligation of the fragments are simultaneously prepared.

Keith et al teach et al discloses a method of simultaneously preparing DNA fragments by restriction enzyme digest and ligating said fragments to another nucleic acid of desired function (see column 2-6).

One of ordinary skill in the art would have been motivated to have modified the method of any one of the primary reference by carrying out the preparation and ligation steps simultaneously because Keith discloses the convenience and benefits of simultaneous restriction digestion of DNA and ligation of digestion fragments to another nucleic acid of desired function. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the claimed invention to carry out the claimed method with a reasonable expectation of success.

Response to Arguments

18. Applicant traverses the rejection on the following grounds: Applicant states that none of the above cited references, either alone or in combination, disclose or suggest the claimed invention. Applicant states that in particular, none discloses or suggested

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either the claimed method for generating short DNA fragments or the short DNA fragments which are obtained by the claimed method. Applicant summarizes the instant invention and states that none of the recited references describes or suggest the selective fragmentations of nucleic acids to be analyzed using a combination of two restriction enzymes E1 and E2 and a double stranded adapter AA' which is complementary to the E1 restriction site and is chosen so that the 3' end of the E1 enzyme restriction site contains the first base pairs only bit not the entire sequence of the E2 enzyme recognition site.

Applicant summarizes the teaching of Sapolsky et al and states that method disclosed by Sapolsky et al does not entail the digestion of a subset of fragments since all of the ligated fragments have the type IIS RE recognition site sequence.

Applicant summarizes the teaching of Yu et al and teaches that the method disclosed by Yu et al does not entail the digestion of a subset of fragments since all of the ligated fragments have the type IIS RE recognition site sequence.

Applicant summarizes the teaching of Van Eijk et al and teaches that the method disclosed by Van Eijk et al does not entail the digestion of a subset of fragments since all of the ligated fragments have the type IIS RE recognition site sequence.

Applicant summarizes the teaching of Kato et al and teaches that the method disclosed by Kato et al does not entail the digestion of a subset of fragments since all of the ligated fragments have the type IIS RE recognition site sequence.

Applicant states that one skilled in the art would not have been put in possession of the claimed invention by any single cited reference or combination thereof.

With regards to the rejection under 35 USC 103(a), Applicant states that as noted above, none of the references would have put one skilled in the art in possession of the claimed invention.

Examiner's response

19. All of the arguments have been thoroughly reviewed and considered but are not found persuasive for the reasons that follow: While the Examiner acknowledges the Applicant's arguments, it is noted that the arguments are not commensurate fully in scope with the claims. Firstly, neither the claims nor specification provides a limitation definition for an E1 or E2 restriction enzyme restriction site. Likewise, neither the claims nor specification excludes the use of a type IIS RE recognition site sequence. In fact, the claims recited that the enzymes cleaves frequently and the other rarely, which encompasses type IIS restriction enzymes and hence would inherently encompass fragments having type IIS RE recognition site sequence. Additionally, the specification at page 11-12 provides examples of type IIS restriction enzymes that are capable of use in the instant invention. Applicant's arguments are not found persuasive to overcome the rejections noted above.

Conclusion

20. No claims are allowed. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CYNTHIA B. WILDER whose telephone number is (571)272-0791. The examiner can normally be reached on a flexible schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cynthia B. Wilder/
Examiner, Art Unit 1637

/GARY BENZION/
Supervisory Patent Examiner, Art Unit 1637